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have elapsed. When response is attained, dosage should be gradually reduced until maintenance level is achieved.

(2) *Indications for use.* For use in dogs as an anti-inflammatory agent.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[57 FR 4718, Feb. 7, 1992, as amended at 60 FR 57832, Nov. 22, 1995; 63 FR 148, Jan. 5, 1998]

§ 520.1900 Primidone tablets.

(a) *Specifications.* Each tablet contains 50 or 250 milligrams of primidone.

(b) *Sponsor.* See No. 000010 in § 510.600(c) of this chapter for use of 250 milligram tablets; see No. 000856 in § 510.600(c) of this chapter for use of 50 and 250 milligram tablets.

(c) *Conditions of use in dogs—(1) Amount.* Twenty-five milligrams of primidone per pound of body weight (55 milligrams per kilogram of body weight) daily.¹

(2) *Indications for use.* For the control of convulsions associated with idiopathic epilepsy, epileptiform convulsions, viral encephalitis, distemper, and hardpad disease that occurs as a clinically recognizable lesion in certain entities in dogs.¹

(3) *Limitations.* The tablets may be administered whole or crushed and mixed with the food. When convulsions are frequent, the dosage should be divided and administered at intervals. Reduction in dosage should be made gradually and never be abruptly discontinued. Do not use in feline species, as primidone appears to have a specific neurotoxicity in cats. Federal law restricts this drug to use by or on the order of a licensed veterinarian.¹

[42 FR 61594, Dec. 6, 1977, as amended at 43 FR 55386, Nov. 28, 1978; 46 FR 8467, Jan. 27, 1981; 46 FR 57477, Nov. 24, 1981; 53 FR 40727, Oct. 18, 1988; 56 FR 37473, Aug. 7, 1991; 62 FR 35076, June 30, 1997]

¹These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

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§ 520.1920 Prochlorperazine, isopropamide sustained release capsules.

(a) *Specifications.* Prochlorperazine, isopropamide sustained release capsules contain either:

(1) 3.33 milligrams of prochlorperazine (as the dimaleate) and 1.67 milligrams of isopropamide (as the iodide), or

(2) 10 milligrams of prochlorperazine (as the dimaleate) and 5 milligrams of isopropamide (as the iodide).

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.

(c) *Conditions of use.* (1) The drug is used for the treatment of dogs in which gastrointestinal disturbances are associated with emotional stress.

(2)(i) Capsules described in paragraph (a)(1) of this section are administered orally to dogs weighing from 4 to 15 pounds at the rate of 1 capsule twice daily. These capsules are administered orally to dogs weighing from 16 to 30 pounds at the rate of 1 or 2 capsules twice daily. For dogs weighing less than 4 pounds, administer orally an appropriate fraction of the contents of one of these capsules.

(ii) Capsules described in paragraph (a)(2) of this section are given to dogs weighing 30 pounds and over at the rate of 1 capsule twice daily.

(3) For use only by or on the order of a licensed veterinarian.

[40 FR 13838, Mar. 27, 1975, as amended at 56 FR 50653, Oct. 8, 1991; 60 FR 55659, Nov. 2, 1995]

§ 520.1921 Prochlorperazine, isopropamide, with neomycin sustained-release capsules.

(a) *Specifications.* Each capsule contains either:

(1) Capsule No. 1: 3.33 milligrams of prochlorperazine (as the dimaleate), 1.67 milligrams of isopropamide (as the iodide), and 25 milligrams of neomycin base (as the sulfate); or

(2) Capsule No. 3: 10 milligrams of prochlorperazine (as the dimaleate), 5 milligrams of isopropamide (as the iodide), and 75 milligrams of neomycin base (as the sulfate).

(b) *Sponsor.* See No. 000069 in § 510.600(c) of this chapter.